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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/523,473 | 01/03/2006 | David S. Potter | 663490-015 | 1846 |

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DICKINSON WRIGHT PLLC
38525 WOODWARD AVENUE
SUITE 2000
BLOOMFIELD HILLS, MI 48304-2970

| EXAMINER | |
|---|---|
| CAMPBELL, VICTORIA P | |

| ART UNIT | PAPER NUMBER |
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| 3763 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/523,473 | POTTER ET AL. | |
| | Examiner | Art Unit | |
| | VICTORIA P. CAMPBELL | 3763 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *09 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-9,11-14,16-19,26-43,45-52 and 57* is/are rejected.

7)☒ Claim(s) *10,15,20-25,44 and 53-56* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 February 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :2/4/05 5/19/05 7/3/06 9/5/06 2/9/07 4/17/07 5/29/07 1/24/08.

## DETAILED ACTION

### *Election/Restrictions*

Applicant's election with traverse of Group I, claims 1-37 as defined by the examiner, in the reply filed on April 9, 2009 is acknowledged. The traversal is on the ground(s) that the drug delivery device of Group I and the packaged drug of Group II share a "common functional feature", and that the method of Group III further comprises the aforementioned common functional feature. Without conceding the propriety of the rejection, the examiner hereby withdraws the previous restriction requirement and will examine all claims presented in the case.

This is the initial Office Action based on the 10/523473 application filed January 3, 2006. Claims 1-57 as elected are currently pending and considered below.

### *Drawings*

1. The drawings are objected to because the drawings are generally informal and reference characters can be difficult to distinguish (especially between characters having "6" or "8"). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the

replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Specification***

2. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet **within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length** since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

3. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

### *Claim Objections*

4. Claim 22 is objected to because of the following informalities: the claim is generally difficult to understand and it appears it is missing punctuation, and or articles such as "a", "an", or "the" in various places. Appropriate correction is required.

5. Claim 57 objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should be in the alternative form. The claim presented by the applicant provides separate conditions regarding claim 1 and claim 38. See MPEP § 608.01(n).

### *Claim Rejections - 35 USC § 112*

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claim 57 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claim does not contain steps on how one would deliver a drug to a human or animal body using the prepackaged drug of claim 38 because the method claim does not provide for any delivery device to be used in combination with the prepackaged drug, and therefore the method is not enabled.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claim 7, line 5 recites the phrase "said housing further comprising". It is unclear to the examiner whether the "housing" referred to is the housing of the drug delivery device or the housing of the packaged drug. For purposes of examination, the examiner has interpreted "said housing" in line 5 to mean "said packaged drug housing" for continuity with claim 38.

***Claim Rejections - 35 USC § 103***

11. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 1-7, 9, 11-14, 16-19, 26-31, 34-38, 41-43, 45, 47, and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over USPN 2,398,544 to Lockhart.

Regarding the above claims, Lockhart teaches a drug delivery device comprising a housing (C); a pre-primed means for generating a force (24); a means for transmitting said force (20); a means for triggering and/or priming the device (S); an upper barrel (26 and C above crosspiece 28) housing the force generating means; a lower barrel (C below crosspiece 28 and 10) housing a packaged drug (A) and the means for transmitting force. Lockhart further teaches a means for receiving the packaged drug (10). Lockhart also teaches that the packaged drug is slidably disposed in the means for receiving the packaged drug (collar 10 slides over the ampoule A), that the means for generating the force is a coil spring (24), and that the force is adjustable by a screw cap and compression bar (cap 26 can screw and unscrew to change the tension on the spring 24 between it and compression bar 22). Lockhart also teach that the device is primed and actuated by two separate actions (priming by moving the sleeve toward the cap; actuating by moving the sleeve toward the dispensing end), that the drug is in a contained form (A) wherein the drug is a liquid contained by a membrane (A and 18), that the packaged drug is an integral part of the device (without it, no injection can take place), that there is a positive lock retention system (threads, Fig. 2) ensuring the

packaged drug does not come away from the device, and that the means for triggering is an actuation button or like element (sleeve S).

Lockhart further teaches a packaged drug comprising a packaging containing a drug comprising a housing (A) having a channel running there through (14), in which is disposed a drive pin (42), a skin piercing means (44) and the drug (44), said housing further comprising a region allowing the packaged drug to be slidably mounted in the drug delivery device (wall of ampoule) and an end adapted to engage and tension the skin (distal end of the ampoule). Lockhart further teaches that the drive pin has a flat head (42), that the means for transmitting the force is a striker (20), that the striker is a hammer (20), wherein a region of the striker is shaped to fit a correspondingly shaped surface in a wall separating the upper and lower barrels (28) such that the striker is aligned to strike the drive pin or other element in the packaged drug on actuation (Figs. 2-3). Lockhart also teaches that the housing is adapted to ensure the packaged drug positively locks to the device yet is free to slide therein (threads, see Fig. 2), that the packaging is substantially T-shaped (Fig. 2), and that the housing is made up of two parts (A and 18) and holds the drug in a contained state (Fig. 2)

Lockhart also teaches drug delivery via the device described above as shown in Figure 3.

Lockhart fails to explicitly teach or disclose that the velocity of the drug is less than 20 m/s, or moreover less than 10 m/s, or that the delivery force is 10-40N. It would have been obvious to one having ordinary skill in the art at the time the invention was made to choose the above operating parameters since it has been held that where the

general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Lockhart also fails to explicitly teach or disclose that the wall separating the upper and lower chambers has a frustoconical surface that cooperates with the frustoconical shoulder region (40) of the striker. It would have been an obvious matter of design choice to make the interior surface frustoconical, since applicant has not disclosed that doing so solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with the straight surfaces explicitly disclosed by Lockhart.

Lockhart also fails to explicitly teach or disclose that the upper and lower housing are made of separate components. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the components separately, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. Nerwin v. Erlichman, 168 USPQ 177, 179.

Lockhart fails to explicitly teach or disclose that the drug delivery device is packaged in a foil pouch to prevent ingress of moisture, oxygen, etc. However, this is a practice common in the art of drug delivery devices and is therefore considered obvious to one having ordinary skill in the art.

14. Claims 8, 32, 33, 39, 40, 46, and 48-52 rejected under 35 U.S.C. 103(a) as being unpatentable over Lockhart as applied to the above claims, and further in view of USPN 4,968,302 to Schluter et al.

Regarding the above claims, Schluter et al further teach a packaged drug containing a skin piercing means (3) which is a needle, that the tip of the needle is positioned a few mm from the end of the packaging such that it is moving when it contacts the skin (Figs. 5a and 5b), and that there end about the exit end of the channel is in the form of an annular ring having an exit with a depth and width from 1.5-6mm (needle creates channel as shown in Fig. 5b). Schluter et al further teach that the needle is disposed in the channel towards an end and a contained liquid drug is disposed in the channel there above (Fig. 5a), and that the contained liquid drug comprises a receptacle slidably disposed and having a puncturable base (29) a top sealable with the drive pin (22) for pushing the receptacle against the needle (Fig. 5a) and the needle into the human or animal body (Fig. 5b). Schluter et al further teach a resilient spacer between the needle and receptacle (29), that the needle is automatically withdrawn after use (after an injection the needle is inherently removed from the patient), and that the needle is sharp at both its ends (Fig. 5a).

Schluter et al do not disclose a drug splinter or pioneer projectile, however, such injection modes were known in the art of injection at the time of invention and represent a simple substitution of known parts and therefore would have been an obvious variation on the injection cartridge of Schluter et al.

At the time of invention, it would have been obvious to one having ordinary skill in the art to substitute the ampoule of Schluter et al into the drug delivery device of Lockhart because doing so is simply substituting one known drug package for another to achieve the predictable result of injectable drug delivery into a patient.

***Allowable Subject Matter***

15. Claims 10, 15, 20-25, 44, and 53-56 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VICTORIA P. CAMPBELL whose telephone number is (571)270-5035. The examiner can normally be reached on Monday-Thursday, 7-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Victoria P Campbell
Examiner, AU 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763